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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/530,112 07/10/95 MATSUBARA

K 215/070

EXAMINER

HM22/0509

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CAMPELL, B

ART UNIT

PAPER NUMBER

1632

DATE MAILED:

05/09/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

8/530,112

Applicant(s)

Matsubara et al

Examiner

Campbell

Group Art Unit

1632

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 2/22/00
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1, 3, 13, 21, 29-68 is/are pending in the application.
- ☐ Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1, 3, 13, 21, 29-68 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of References Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

Office Action Summary

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The response filed February 22, 2000 has been entered.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, 3, 13, 21 and 29-68 are rejected under 35 U.S.C. § 101 because the claimed invention is not supported by either a well established utility or a specific, substantial utility.

The disclosed utilities for the claimed polynucleotides are 1) detecting the expression status of mRNAs, 2) detecting and diagnosing diseases and viral infections, 3) identifying cell types, and 4) cloning genes expressed in a tissue-specific manner. The specification discloses partial cDNA sequences (ESTs). The specification does not appear to disclose the identity or biological activity of any protein encoded by the full length cDNAs corresponding to the ESTs. Thus, with regard to utility 4, specific utility is lacking because a method of making a material does not have a specific asserted utility in those instances where the final product has no disclosed or well established utility. Utility 2 is not a substantial utility because there is no demonstrated correlation between expression of any of the claimed ESTs and any disease or virus. While it is not inconceivable that the polynucleotides might some day be used for these purposes, these utilities are not readily available, i.e. further research is required on the invention itself before it can be used for these purposes. Utility 1 is also not a substantial utility because it is essentially further research on the invention itself. Utilities 3 and 4 are not specific utilities because each cell type in the human body is expected to express a number of genes which are expressed predominantly in that cell type. Because any cell- or tissue-specific sequence can be used to identify cell types or isolate tissue-specific genes, these are not considered specific utilities.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Written Description

Claims 1, 3, 13, 21 and 29-68 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, as previously stated (paper 12, p. 2).

Applicants argue that they were in possession of shorter sequences contained within the elected EST sequences. The Examiner agrees. The basis for the rejection is the open claim language (i.e. "comprising"). The claims encompass a large genus of polynucleotides, including the subgenera of full length cDNAs and genes. The specification does not disclose the complete structure of any full length cDNA or gene, nor are any other identifying characteristics disclosed. Thus the written description requirement is not satisfied for these subgenera, nor for the larger genus recited in the claims.

Applicants argue that one skilled in the art could obtain longer sequences. The Examiner agrees that one could simply add nucleotides at random to produce longer sequences comprising the elected ESTs. The primary concern, however, is that the claims encompass full length cDNAs, longer partial cDNAs, and genomic sequences which are not described in the specification. The fact that one could isolate such polynucleotides does not indicate that Applicants were in possession of them at the time of filing.

Enablement

Claims 1, 3, 13, 21 and 29-68 are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth in the rejection under § 101 above, one skilled in the art clearly would not know how to use the claimed invention.

In the event that Applicants might overcome the rejection under § 101, the following ground of rejection would still apply.

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Claims 1, 3, 13, 21 and 29-68 are rejected under 35 U.S.C. 112, first paragraph because the specification is enabling only for claims limited to polynucleotides consisting of the elected sequences, or fragments thereof, as previously stated (paper 12, pp. 3-4).

Applicants argue that the elected sequences can be used as probes, primers, etc. This argument is not persuasive because the specification does not teach what the probes and primers will detect or isolate. Thus this is not a specific utility, as discussed above.

Applicants argue that longer sequences can be obtained by methods routine in the art. This argument is not persuasive because isolating the full length cDNAs or genomic clones would require further experimentation on the invention itself. If such experimentation is required, then the claimed invention does not have a substantial utility (i.e., the utility is not immediately available).

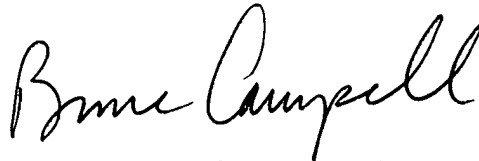
Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce Campell, whose telephone number is 703-308-4205. The examiner can normally be reached on Monday-Thursday from 8:00 to 4:30 (Eastern time). The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jasmine Chambers, can be reached on 703-308-2035. The FAX phone numbers for group 1600 are 703-308-4242 and 703-305-3014.

An inquiry of a general nature or relating to the status of the application should be directed to the group receptionist whose telephone number is 703-308-0196.



**BRUCE R. CAMPELL
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